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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,032	04/26/1999	GUY SERRE	3339-392	6404

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EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/28/2002

LB

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,032

Applicant(s)

Serre et al.

Examiner

Hope Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 2, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other:

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DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-6) in Paper No. 17 is acknowledged.
2. The traversal is on the ground(s) that the "present application is the U.S. National Stage of a PCT application and it appears that the examiner has applied the U. S. standards, rather than the PCT Unity of Invention Standards. The common technical feature which is shared by all of the claims is the artificial antigen of claims 1-4. This same technical feature is present in claims 7-10. Thus, it clearly appears that the claims of Group I and II form a single general inventive concept". Applicant's arguments have been considered but are not persuasive as under PCT Rules applicant is entitled to the first product and a method of making and using that product. The claims encompassed by Group I has the product (artificial antigen), a use of the antigen (method of use) and an antigenic composition. Thus Group I consists of the product and method of use of the product. Group II encompasses a method of detecting autoantibodies specific for rheumatoid arthritis by using the product of Group I. Note also that the product does not avoid the prior art which demonstrates that no special technical feature is present. If the product is deemed allowable, then applicant would be entitled to a rejoinder of the alternate method claims under *In Re Ochai*. Therefore, the lack of unity found is proper and applicant's contention that U.S. rather than PCT standards have been applied is incorrect as PCT Rule 13 grants applicant

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the first product, method of making and using that product which is encompassed in Group I.

Thus, the holding of lack of unity is proper and final.

Priority

3. It is noted that applicant has claimed priority to application numbers PCT/FR97/01541, filed September 1, 1997 and 9610651, filed August 30, 1996, however, certified copies of the priority documents have not been received. ✓

Abstract

4. The abstract is objected to because this application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. ✓

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- ✓ 5. Claim 5 is rejected under 35 U.S. C. 101 because the claimed recitation of use, without setting forth any steps involved in the method/process, results in an improper definition of a method/process. Note that "A use" is not a statutory class of invention.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites "all or part" of a sequence derived from that of a filaggrin unit, instead of "obtained from". In addition, it is unclear what part of the sequence is referred to (see also claims 3-5). Additionally, the claimed recites that "at least one arginine residue is replaced with a citrulline residue" and no sequence is not recited in the claim (see also claim 3).

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Claim 2 is indefinite because the claims recites, "...amino acids 144 to 314 and 76 to 144 without the corresponding sequence identifier (SEQ ID NO:). In addition the claim recites "amino acids" rather than "amino acid residues". Note also that the claim is redundant for reciting "or alternatively". It is suggested that only one term is recited in the claim.

Claim 6 is indefinite because the claim recites "and/or" and it is unclear if the slash mark is suppose to mean "and" or "or". Claim 6 is also indefinite because the claim does not indicate whether the molecular weight recited was measured by SDS-PAGE, for example.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al. (Journal of Clinical Investigation, vol. 92, no. 3, pages 1387-1393, 1993).

Simon teach purification of a 40 kDa protein which represents a mixture of neutral or acid isoforms of filaggrin. This protein also is recognized by the autoantibodies directed against the filaggrin. Simon also teach that the protein contains more citrulline residues than filaggrin and

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discloses that the conversion of arginine residues to citrulline is the cause of a reduction in pI and the slight increase in molecular weight observed in filaggrin. The reference also teach that the autoantibody against filaggrin is useful to serologically diagnose RA (rheumatoid arthritis). Thus, the claimed invention is anticipated by this reference (see Table 1 and pages 1387-1393).

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response.

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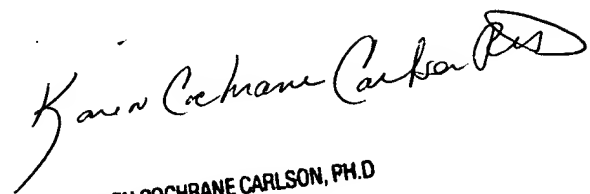
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The faxing of such papers must conform with the notice published in the Official Gazette, 1096
OG (November 15, 1989).

Hope A. Robinson, MS^{HP}

Patent Examiner


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER